



March 8, 2023

The information presented in this document provides interested stakeholders with advance notice of active ingredients under review for renewal of approval in the EU and highlights which substances that have **expired**, are expected to **expire**, may have **restricted renewal** or **non-renewal of approval**. The green arrows reflect where a substance is in the EU review process as of **February 28, 2023**.

In the European Union active ingredients must be reviewed every 10-15 years. The review process takes three or more years to complete. Registrants must submit an application for renewal no later than thirty-six months prior to the expiration date. The figure below highlights the general timeline between the main steps of the process. During these reviews, substances are checked against EU cut off criteria. Triggering the cut off criteria is likely to result in the removal of the pesticide from use in the EU. It can also result in the elimination of the associated MRLs.

The pesticide review process monitored here is different from the MRL review process (Article 12 Reviews). MRL-specific reviews are notified on a rolling basis according to the schedule shared at the end of this report.

Application	Renewal Assessment Report	EFSA Peer Review	EC Draft Regulation (PAFF)	WTO/TBT Notification	Commission Regulation (EU)	
13 months 11 months 6 months 3 months+ 4 months+						

APPLICATION FOR RENEWAL – EXPECTED TO EXPIRE (Up to February 2024)

Chemical companies must support the review of their substance. If they do not, the active ingredient will automatically expire in the EU on a set date. For the substances below, registrants **have not submitted the application** for renewal of approval or **have withdrawn the application** and **approval will expire.** Corresponding MRLs may be affected. The substance's expiration date is outlined in parentheses.

- **Bacillus firmus I-1582*** (September 30, 2023)
- **Spiromesifen** (September 30, 2023)
- Trichoderma atroviride (formerly T. harzianum) strain IMI 206040* (September 30, 2023)

APPLICATION FOR RENEWAL - EXPIRED (March 2022 – February 2023)

Substances in this section have already expired due to non-submission of application for renewal or withdrawal of application for renewal. This list includes substances that have expired in the last year. Corresponding MRLs may be affected. Expiration date is outlined in parentheses.

- **Bispyribac** (July 31, 2022)
- Plant oils /Citronella oil* (August 31, 2022)

^{*}Substance is exempted from a tolerance in the United States





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UP NEXT FOR REVIEW (Up to February 2024)

Under the EU pesticide review program, the substances listed in this section are scheduled to go through the periodic review process. They have upcoming deadlines for the submission of the application for renewal.

- Methoxyfenozide (March 31, 2023)
- **Pinoxaden** (June 30, 2023)
- Cyantraniliprole (September 14, 2023)
- **Isofetamid** (September 15, 2023)
- Bacillus amyloliquefaciens MBI 600* (September 16, 2023)

STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED (SCoPAFF)

Based on the European Food Safety Authority (EFSA) conclusions, the European Commission has proposed the substances in this section for **non-renewal** or **restricted renewal**. They are now **under consideration** by the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) as available in the **January 25-26** and **March 22-23, 2023**, meeting agendas. Drafts are first presented for discussion and subsequently for a vote by the Committee. Draft proposals may be notified to the World Trade Organization (WTO) prior to the Committee's final vote. In these cases, substances are listed below and in the next section.

Drafts presented for discussion

Captan

Drafts presented for a vote

- Oxamyl
- Ipconazole

WTO NOTIFICATION (March 2022 – February 2023)

The substances in this section have been notified to the **WTO** as proposed for non-renewal or restricted renewal. After the comment period, the Commission will analyze the comments received and publish the Implementing Regulation. Notification date is outlined in parentheses (). Please refer to the draft Commission Regulation for the full explanation of the justification for the restricted or non-renewal of approval.

Proposed non-renewal

Ipconazole: proposed withdrawal of approval due to high long-term risk to birds and classification as toxic for reproduction category 1B. (January 10, 2023)

Oxamyl: proposed non-renewal of approval due to high risk for all the representative uses assessed to exceed the acceptable operator exposure level, exceedance of the acute reference dose, others. (January 16, 2023)

Proposed restricted renewal

Captan: proposed restricted renewal of approval to permanent greenhouse use only. (September 28, 2022)





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COMMISSION IMPLEMENTING REGULATION (March 2022 – February 2023)

The Commission has published the final decision on non-renewal or restricted renewal in the EU for the substances in this section. EU MRLs may be subject to change as a result. Implementing regulation publication date is outlined in parentheses (). Please refer to the published Commission Regulation for the full explanation of the justification for the restricted or non-renewal of approval.

Non-renewal

Benfluralin: non-renewal based on long-term risk to birds and mammals including the risk from secondary poisoning of earthworm eating birds and mammals, as well as the genotoxic potential of an impurity could not be excluded. (January 23, 2023)

Restricted renewal

Sulfoxaflor: restricted renewal of approval to permanent greenhouse uses only. (April 28, 2022)

Bifenazate: restricted renewal of approval to non-edible crops in permanent greenhouses. (May 3, 2022)

MRL CHANGES (March 2022 - February 2023)

As a **result of non-renewal** or **expiration of approval**, restrictive MRLs have either been proposed (WTO notification) or implemented (Commission Regulation) for the substances below.

WTO Notification:

- **Cyromazine**: WTO notification G/SPS/N/EU/582. (July 21, 2022)
- Topramezone: WTO notification G/SPS/N/EU/582. (July 21, 2022)
- **Triflumizole**: WTO notification G/SPS/N/EU/582. (July 21, 2022)
- Calcium phosphide*: WTO notification G/SPS/N/EU/582. (July 21, 2022)
- **Phosmet**: WTO notification G/SPS/N/EU/606. (December 14, 2022)
- **Bifenazate**: WTO notification G/SPS/N/EU/609. (January 17, 2023)
- Carboxin: WTO notification G/SPS/N/EU/616. (February 23, 2023)
- **Diuron**: WTO notification G/SPS/N/EU/617. (February 24, 2023)
- **Etoxazole**: WTO notification G/SPS/N/EU/617. (February 24, 2023)

Import tolerances and/or some Codex MRLs were maintained for the following substance:

o **Methomyl**: WTO notification G/SPS/N/EU/617. (February 24, 2023)

Implementing Regulation:

- Thiram: Commission Regulation 2022/1406 on August 3, 2022. Effective date: February 28, 2023
- Bromoxynil: Commission Regulation 2023/128 on January 19, 2023. Effective date: August 8, 2023
- Chlorsulfuron: Commission Regulation 2023/128 on January 19, 2023. Effective date: August 8, 2023

^{*}Substance is exempted from a tolerance in the United States





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MRL CHANGES (continued)

As a **result of non-renewal** or **expiration of approval**, restrictive MRLs have either been proposed (WTO notification) or implemented (Commission Regulation) for the substances below.

Implementing Regulation:

- Clothianidin: Commission Regulation 2023/334 on February 15, 2023. Effective date: March 7, 2026
- Thiamethoxam: Commission Regulation 2023/334 on February 15, 2023. Effective date: March 7, 2026
- **Sodium aluminum silicate**: Commission Regulation 2023/377 on February 22, 2023. *Effective date: September 14, 2023*
- Triadimenol: Commission Regulation 2023/377 on February 22, 2023. Effective date: September 14, 2023

Import tolerances and/or some Codex MRLs were maintained for the following substance:

- O Cyfluthrin: Commission Regulation 2023/173 on January 27, 2023. Effective date: August 16, 2023
- o Beta Cyfluthrin: Commission Regulation 2023/173 on January 27, 2023. Effective date: August 16, 2023

EU EARLY ALERT – ARTICLE 12 MRL REVIEW

The Article 12 of Regulation (EC) No. 396/2005 provides for the review of all MRLs established in the European Union. EFSA publishes a <u>progress report</u> that lays out the expected timeline for MRL-specific reviews (start of data collection and conclusion of EFSA's Reasoned Opinion). The table below lists active ingredients of interest to U.S. stakeholders that have started or are expected to start the MRL review process in 2023, according to information available as of **February 28, 2023**.

The Office of Plant Division at the Foreign Agriculture Service notifies stakeholders at the beginning of the MRL review process. This early notice provides stakeholders the opportunity to contact registrants and coordinate on actions to support the EU MRL at a critical point of the MRL review process.

Active Substance	Start of MRL Review	Reasoned Opinion
Difenoconazole	09/17/2021	05/28/2023
Zoxamide	09/15/2022	09/15/2023
Gamma-cyhalothrin	01/15/2023	02/15/2024
Clopyralid	06/15/2023	06/15/2024

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